

Applicant: Wen-Tien Chen
Application Serial No. 10/727,211
Filing Date: December 3, 2003
Docket: 178-295 CIP/CON
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REMARKS

Prior to the present amendment, claims 64 through 72 were pending. By this amendment, applicant has amended claims 64, 66, and 68. Claims 64 through 72 are currently pending.

Notice of Non-Compliant Amendment

In response to the Notice of Non-Compliant Amendment dated October 18, 2006, applicant submitted a "corrected section" of the preliminary amendment to include the markings that were previously omitted. The "corrected section" was submitted on November 15, 2006, which was within one month from the date of the Notice.

Claim Objections

The examiner objected to claims 64 through 72 for being alternatively drawn to the subject matter of non-elected species of invention. Applicant will cancel the non-elected species at the appropriate time if no generic claim is found to be allowable.

Rejections under 35 U.S.C. § 112, second paragraph

Claims 64 through 72 were rejected under 35 U.S.C. § 112, second paragraph. According to the examiner, the claims are indefinite because of the use of the designation E19 as the sole means of identifying the anti-DPPIV antibody to which they refer. The examiner states in the office action, on page 4, item 8, third paragraph, that an amendment of the specification and claims to include the depository accession number of the monoclonal antibody or hybridoma would remedy this issue.

Applicant has amended the specification to add a paragraph that provides the depository accession number of the hybridomas E19 and E26. The added paragraph specifically identifies the biological material deposited, in accordance with 37 CFR

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§1.804(a). Applicant has also amended the claims to include such information. No new matter has been added.

In addition, applicant hereby submits a copy of the declaration under 37 CFR § 1.132, filed on October 8, 2002, filed during the prosecution of the parent application (serial number 09/541,785). The declaration provides the proper assurances for the deposits.

In the declaration, Dr. Chen states that the rat hybridomas E19 and E26, which produce the monoclonal antibody E19 and monoclonal antibody E26, respectively, were deposited in compliance with the Budapest Treaty requirements with American Type Culture Collection (ATCC). The biological materials deposited are readily available to the public if a patent is granted.

Further, applicant submits a copy of Dr. Chen's statement under 37 CFR §1.804(b), which was filed during prosecution of the parent application (serial number 09/541,785). Dr. Chen's statement corroborates the fact that the deposited hybridomas are the biological materials specifically identified in the parent application, from which the present application claims priority.

Accordingly, applicant has provided the proper assurances and amendments for the deposits. Applicant requests that the rejection be reconsidered and withdrawn.

Rejections under 35 U.S.C. § 112, first paragraph

Claims 64 through 72 were rejected under 35 U.S.C. § 112, first paragraph, as failing to comply with the written description requirement. According to the examiner, the application fails to adequately describe the genus of antibodies or antigen-binding fragments that bind specifically to the epitope of DPPIV recognized by monoclonal antibody E19. See page 6, third paragraph of the office action.

Applicant has amended the following recitation in the claims: "A bispecific antibody with binding specificity for a first epitope...wherein the first epitope is ...recognized by E19

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and E26.” The claims now recite the following: “A bispecific antibody comprising an antigen binding portion of monoclonal antibody E19 (ATCC PTA-3378) or E26 (ATCC PTA-3377) that specifically binds to an epitope of a mammalian dipeptidyl peptidase IV...” Accordingly, the rejection is now moot and should be withdrawn.

Claims 64 through 72 were further rejected under the enablement requirements of 35 U.S.C. § 112, first paragraph. According to the examiner, the specification is not enabled “for making or using a bispecific antibody comprising an antigen binding portion of an antibody that binds to the epitope of DPPIV recognized by monoclonal antibody E19 and an antigen binding portion of an antibody that specifically binds to an epitope of seprase.” See page 13, first paragraph of item 11, in the office action.

However, the examiner states that the specification is enabling for “making and using a bispecific antibody comprising an antigen binding portion of monoclonal antibody E19, which specifically binds to an epitope of DPPIV, and an antigen binding portion of an antibody that specifically binds to an epitope of seprase.” See page 13, first paragraph of item 11, in the office action.

With further regard to the claims, the examiner states that it is unclear if a cell line that produces an antibody having the exact structural and chemical identity as any of these antibodies is known and publicly available, or can be reproducibly isolated without undue experimentation. See page 15, last paragraph, of the office action. The examiner, however, states that timely deposit of a hybridoma or other cell line producing the antibody to which the claims are directed would satisfy the enablement requirements of 35 U.S.C. § 112, first paragraph. See page 16, first paragraph, of the office action.

In consideration of the subject matter that the examiner states is enabled by the specification, applicant has amended the claims to recite the following: “an antigen binding portion of monoclonal antibody E19 (ATCC PTA-3378) or E26 (ATCC PTA-3377) that specifically binds to an epitope of a mammalian dipeptidyl peptidase IV.” Regarding the

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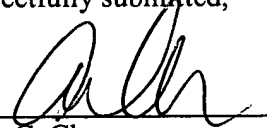
public availability of the E19 and E26 hybridomas, applicant has fulfilled the deposit requirements for the E19 and E26 hybridomas, as explained above.

For the foregoing reasons, applicant respectfully requests that the rejection of the claims under 35 U.S.C. § 112, first paragraph be reconsidered and withdrawn.

Allowance of the pending claims is earnestly requested. If the examiner has any questions regarding this amendment, he is respectfully requested to contact the undersigned at the telephone number set forth below.

If any additional fees are due or any overpayment has been made, please charge or credit Deposit Account No. 08-2461.

Respectfully submitted,



Anna C. Chau
Registration No. 54,637
Agent for Applicants

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6900 Jericho Turnpike
Syosset, New York 11791
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ATCC

10801 University Blvd • Manassas, VA 20110-2209 • Telephone: 703-365-2700 • FAX: 703-365-2745

BUDAPEST TREATY ON THE INTERNATIONAL RECOGNITION OF THE DEPOSIT OF MICROORGANISMS FOR THE PURPOSES OF PATENT PROCEDURE

INTERNATIONAL FORM

RECEIPT IN THE CASE OF AN ORIGINAL DEPOSIT ISSUED PURSUANT TO RULE 7.3 AND VIABILITY STATEMENT ISSUED PURSUANT TO RULE 10.2

To: (Name and Address of Depositor or Attorney)

The Research Foundation of State University of New York
Attn: Wen Tien Chen
T15-053 Health Sciences Center
Stony Brook, New York 11794

Deposited on Behalf of: The Research Foundation of State University of New York

Identification Reference by Depositor:

Patent Deposit Designation

Hybrid between Y3 rat myeloma cells and spleen cells from a rat
immunized with placental proteins: E26

PTA-3377

Hybrid between Y3 rat myeloma cells and spleen cells from a rat
immunized with placental proteins: E19

PTA-3378

The deposits were accompanied by: ☐ a scientific description ☐ a proposed taxonomic description indicated above. The deposits were received May 15, 2001 by this International Depository Authority and have been accepted.

AT YOUR REQUEST: ☒ We will inform you of requests for the strains for 30 years.

The strains will be made available if a patent office signatory to the Budapest Treaty certifies one's right to receive, or if a U.S. Patent is issued citing the strains, and ATCC is instructed by the United States Patent & Trademark Office or the depositor to release said strains.

If the cultures should die or be destroyed during the effective term of the deposit, it shall be your responsibility to replace them with living cultures of the same.

The strains will be maintained for a period of at least 30 years from date of deposit, or five years after the most recent request for a sample, whichever is longer. The United States and many other countries are signatory to the Budapest Treaty.

The viability of the cultures cited above was tested May 22, 2001. On that date, the cultures were viable.

International Depository Authority: American Type Culture Collection, Manassas, VA 20110-2209 USA.

Signature of person having authority to represent ATCC:


Tanya Nunnally, Patent Specialist, Patent Depository

Date: June 27, 2001

cc: Algis Anilionis, Ph.D., Esq.
(Ref: Docket No.: 178-295)

AMERICAN TYPE CULTURE COLLECTION

10801 University Blvd.
Manassas, VA 20110-2209
Telephone: 703-365-2700
Fax: 703-365-2745

FACSIMILE

Date: May 23, 2001

To: Wen-Tien Chen, Ph.D.

Fax Number: 631 444-9092

From: ATCC Patent Depository **Number of pages:** 1 (Including this page)

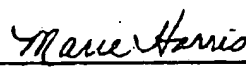
REFERENCE: Patent Deposit (Ref: Docket or Case No.: 178-295)

Hybrid between Y3 rat myeloma cells and spleen cells from a rat immunized with placental proteins: E26 assigned PTA-3377 and
Hybrid between Y3 rat myeloma cells and spleen cells from a rat immunized with placental proteins: E19 assigned PTA-3378.

Date of Deposit: May 15, 2001. Paperwork will be forwarded to you in a few days. An invoice will be sent under separate cover referencing PO # D2876 as follows:

| | |
|----------------------------|---------------|
| Standard storage/informing | \$ 2,300.00 |
| Viability Test | <u>640.00</u> |

Total amount to PTA-3377 to PTA-3378 \$ 2,940.00



Marie Harris, Patent Specialist
ATCC Patent Depository

* Please note: Patent deposit fees have increased effective January 1, 2001. Deposit forms were revised February 2000. Current deposit forms and fees can be obtained from our web site: www.atcc.org.

The information contained in this facsimile is intended only for the use of the individual or entity named above. If the reader of this message is not the intended recipient, you are notified that any dissemination or distribution, except to the intended recipient of this communication, is prohibited. If you have received this communication in error, please call us immediately at the telephone number listed above.

TOTAL P.01

Budapest Treaty Deposits

American Type Culture Collection

1 0801 University Blvd., Manassas, VA 20110-2209

Phone (703) 365-2700; fax (703) 365-2745; e-mail applied-sci@atcc.org

TO DEPOSIT OR TO CONVERT A DEPOSIT TO MEET THE REQUIREMENTS OF THE BUDAPEST TREATY ON THE INTERNATIONAL RECOGNITION OF THE DEPOSIT OF MICROORGANISMS FOR THE PURPOSES OF PATENT PROCEDURE

1. Name of deposit

Hybrid between Y3 rat myeloma cells and spleen cells from a rat immunized with placental proteins.

2. Strain designation (i.e., number, symbols, etc.) E19

3. Is this an original deposit under the Budapest Treaty? Yes

4. Is this a request for a conversion of a deposit already at ATCC to meet the requirements of the Budapest Treaty? No

5. Is this deposit a mixture of microorganisms or cells? No

6. Provide details necessary to cultivate, test for viability, and store deposit. If mixture, provide description of components and a method to check presence. If plasmid, provide name of host and antibiotic resistance.

Stored in liquid nitrogen and cultured as recommended by ATCC. Each of 25 vials contains 3×10^6 cells.
Culture media: 50/50 DMEM/Ham's F12, 10% fetal bovine serum, 5% Nu-Serum™ (Becton Dickinson), 1% Penicillin Streptomycin, 1% L-Glutamine, 1% sodium pyruvate.

7. Provide sufficient description so that ATCC may confirm deposit properties (e.g., Gram negative rod).

a. If deposit is a cell culture, is it being cultured in the presence of antibiotics? If so, please list the antibiotics.

Yes. 1% Penicillin Streptomycin.

b. If deposit is hybridoma, what is the isotype of antibody produced? IgG2a

8. Is this strain hazardous to humans? No Animals? No Plants? No

9. Availability:

a) As of date of deposit or conversion to meet the requirements of the Budapest Treaty, do you wish the deposit to be made available to anyone who requests a culture?

Yes No X

b) As of date of deposit or conversion to meet the requirements of the Budapest Treaty, do you wish the deposit to be made available to requestors which satisfy patent offices in countries not signatory to the Budapest Treaty?

Yes No X

10. Name of individual to notify: Wen-Tien Chen, Ph.D.
Fax: (631) 444-9092 Phone: (631) 444-6948 E-mail: wchen@mail.som.sunysb.edu

11. Purchase Order No. D2876

BILLING ADDRESS, CONTACT PERSON, PHONE AND FAX NUMBER:

John S. Roberts, Ph.D.
Associate Director
Technology Licensing Office
N5002 Melville Library
University at Stony Brook
Stony Brook, NY 11794-3369

Phone: (631) 632-9077 Fax: (631) 632-1505

Name, address, telephone and facsimile number of your attorney of record.

Algis Anilionis, Ph.D., Esq.
Hoffman & Baron, LLP
6900 Jericho Turnpike
Syosset, NY 11791


Phone: (516) 822-3550 Fax: (516) 822-3582 (Docket No. 178-295)

13. Deposited on behalf of:

The Research Foundation of State University of New York

I understand and agree that the deposit may not be withdrawn by me for a period specified in Rule 9.1 of the Budapest Treaty (at least 30 years after the date of deposit or 5 years after the date of the most recent request for the deposit, whichever is longer), and that if a culture should die or be destroyed during the life of the patent or the period of time so specified, it is my responsibility to replace it with a living culture of the same organism or cell. In the cases of viruses, cell cultures, plasmids, embryos, and seeds, it is my responsibility to supply a sufficient quantity for distribution for the period of time specified above.

Wen Tien Chen
Typed Name


Signature

5/9/01
Date

Address: T15-053 Health Sciences Center
Stony Brook, New York 11794

ADDRESS SHIPMENTS AND FORM TO THE ATTENTION OF:

Patent Depository
American Type Culture Collection
10801 University Blvd.
Manassas, VA 20110-2209 U.S.A.

STORAGE: Cultures are stored for 30 years from date of deposit or 5 years after the last request for a sample, whichever is longer, as required under the rules of patent offices in most countries.

ATCC USE ONLY:

ATCC DESIGNATION _____ REC'D _____ V.T. RESULT _____

Name of Deposit _____ Strain Designation: _____

Budapest Treaty Deposits

American Type Culture Collection

1 0801 University Blvd., Manassas, VA 20110-2209

Phone (703) 365-2700; fax (703) 365-2745; e-mail applied-sci@atcc.org

TO DEPOSIT OR TO CONVERT A DEPOSIT TO MEET THE REQUIREMENTS OF THE BUDAPEST TREATY ON THE INTERNATIONAL RECOGNITION OF THE DEPOSIT OF MICROORGANISMS FOR THE PURPOSES OF PATENT PROCEDURE

1. Name of deposit.

Hybrid between Y3 rat myeloma cells and spleen cells from a rat immunized with placental proteins.

2. Strain designation (i.e., number, symbols, etc.) E26

3. Is this an original deposit under the Budapest Treaty? Yes

4. Is this a request for a conversion of a deposit already at ATCC to meet the requirements of the Budapest Treaty? No

5. Is this deposit a mixture of microorganisms or cells? No

6. Provide details necessary to cultivate, test for viability, and store deposit. If mixture, provide description of components and a method to check presence. If plasmid, provide name of host and antibiotic resistance.

Stored in liquid nitrogen and cultured as recommended by ATCC. Each of 25 vials contains 3×10^6 cells.
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Yes No X

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Syosset, NY 11791

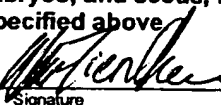
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